EXHIBIT B

Food and Drug Administration
OFFICE OF CRIMINAL INVESTIGATIONS
MEMORANDUM OF INTERVIEW

CASE NUMBER:	2021-SFC-715-0234
CASE TITLE:	CYTODYN, INC
DOCUMENT NUMBER:	303219
PERSON INTERVIEWED:	SUZANNE STRAYHORN
PLACE OF INTERVIEW:	Microsoft Teams Videoconference
DATE OF INTERVIEW:	10/13/2022
TIME OF INTERVIEW:	Approx. 7:38AM - 9:48AM
INTERVIEWED BY:	SA Mather and Trial Attorney O'Neill
OTHER PERSONS PRESENT:	Christopher Fenton, Joshua Debold, Leo Wise, Howard Kim, Daniel Parker, Kevin Towers, Michaela Ausbrooks and Karen Towns

On October 13, 2022, SUZANNE STRAYHORN (STRAYHORN) was interviewed virtually via Microsoft Teams. Present during the interview were: United States (U.S.) Department of Justice (DOJ), Criminal Fraud Section Trial Attorneys Michael O'Neill, Christopher Fenton and Joshua Debold; Assistant United States Attorney Leo Wise; U.S. Securities & Exchange Commission (SEC) Senior Counsel Howard Kim (Kim); Federal Bureau of Investigation (FBI) Special Agent (SA) Daniel Parker; U.S. Postal Inspection Service Inspector Kevin Towers; Food and Drug Administration (FDA) Office of Criminal Investigations SA Maridehl Mather; DOJ Criminal Division, Criminal Fraud Paralegal Michaela Ausbrooks; and U.S. FDA Office of Chief Counsel Associate Chief Counsel Karen Towns.

Prior to the initiation of the interview, STRAYHORN was advised of the identities of the interviewers and the nature of the interview and that she was to be truthful during the interview.

STRAYHORN stated she understood and provided the following information:

STRAYHORN received a master's degree in anatomy from the University of Maryland Dental School. STRAYHORN then worked as a study coordinator at the Shock Trauma Center at the University of Maryland in the Neurotrauma Division. Prior to working for the FDA, STRAYHORN worked at Zeneca Pharmaceuticals, now known as AstraZeneca, where STRAYHORN worked on the drug, Diprivan. STRAYHORN then worked as a project manager at a small contract research organization (CRO) in North Carolina and then to a larger CRO company called, Ikon Development Solutions. STRAYHORN then worked for a small biotech company, Guilford Pharmaceutical (Guilford), in Maryland. STRAYHORN then left Guilford and started working for another CRO called, ICON, for six years before starting her job with the FDA in 2014.

In January of 2014, STRAYHORN was hired by the FDA as a regulatory project manager (RPM). STRAYHORN's primary role was to provide regulatory expertise to the teams, to be a project manager, drive goals, follow the goals, and timelines. STRAYHORN was the interface between the pharmaceutical companies/CROs and the FDA reviewers.

For the purpose of this interview, STRAYHORN was the interface between CYTODYN, INC. (CYTODYN), being the sponsor, and its representative and CRO being Amarex Clinical Research, LLC (Amarex), and the FDA.

Sponsors used to be able to reach out to the FDA reviewers/doctors directly, which created the “he said – she said” problems. STRAYHORN believed that the RPM role was created to avoid those issues. As the RPM, all communications between CYTODYN/Amarex and the FDA went through STRAYHORN. STRAYHORN stated that a lot of documents, specifically communications between the FDA and CYTODYN/Amarex, were signed by STRAYHORN, but it did not mean she wrote the contents of the documents.

• Document: FDA Statement of Leronlimab Issued on May 2021 (the Statement)

STRAYHORN was familiar with the Statement. STRAYHORN believed that the Statement was issued because there was misinformation being presented to the public about leronlimab as the COVID-19 indication. As a result of those information, there was lot of activity and “chatter,” about the drug, and a lot of people were reaching out to the Division Director Debra Birnkrant and Deputy Commissioner Janet Woodcock for access for the product, for which there was no evidence that it was actually working.

STRAYHORN was aware of the drafting of the document, but STRAYHORN had no role in drafting or reviewing the Statement. Doctor (Dr.) Virginia Sheikh (Sheikh) and the legal group had a role with drafting the Statement. According to STRAYHORN, it took a long time to get the Statement out. The Statement had to be “carefully crafted” and had to be cleared through the clearance process. The Statement was signed at the highest level.

According to STRAYHORN, it is “exceedingly rare” and “highly highly unusual” for the FDA to issue such a public statement.” From internal discussions, STRAYHORN has heard that it was the second time that the FDA had issued such a statement to the public.

STRAYHORN stated that CYTODYN “jumped on the COVID-19 bandwagon really quickly.” There were internal discussions within the FDA that CYTODYN, through Amarex, did not provide the FDA “plausible mechanism of action.” STRAYHORN did not think CYTODYN understood how the drug would work. According to STRAYHORN, the FDA had been looking at CYTODYN’s press releases and the “chatter” that was available in the public since 2016.

STRAYHORN stated that CYTODYN, through Amarex, was not very transparent. Often times, the FDA would find out what they were planning to do by way of their statements through their statements in the public. There were concerns that the information CYTODYN was communicating to the public in regard to the CD10 and CD12 clinical studies were inaccurate and misleading. CYTODYN, in their public statements, presented "data in cohorts of cohorts.”

In 2016 Dr. Oz featured Charlie Sheen (Sheen) on his show, where Sheen presented that he wanted to be in a small drug trial for HIV using leronlimab. This was something the FDA has never seen before. STRAYHORN believed that it was around this time where the FDA had their “Aha! moment,” about CYTODYN and their PRs. STRAYHORN stated that she “probably, more than anybody else, followed this company outside of the FDA” because of the statements that were being made. STRAYHORN stated that “it is dangerous to put misinformation and pump up a drug when sick people are dying, relatives are dying…it was a very scary time.” STRAYHORN was recently diagnosed with cancer and had Googled for information about cancer treatment and “this is not in a setting of a pandemic.” STRAYHORN felt that the FDA Statement was “kinda an alert for those who read it and that to be cautious of what you hear.”

It is important in the medical community, especially during a pandemic, to not put out inaccurate information. STRAYHORN stated, “For at-risk patients and parents that are sick, they would want to do everything…” What CYTODYN was putting out on their PRs sounded pretty good for a lay person. There is danger in putting out information prematurely and it was probably to rally stockholders.

STRAYHORN had been following CYTODYN’s public statements since 2016. It is unusual for the FDA to follow sponsors’ public statements. CYTODYN issued a lot of PRs and according to STRAYHORN this kind of activity happens more with smaller firms.

STRAYHORN did not know how Amarex communicated with CYTODYN. CYTODYN had a lot of activities posted online and "it kinda gave FDA an alert on what might be coming on their workload." STRAYHORN also watched many videos of interviews put out by CYTODYN on Proactive Investors' (Proactive) website. STRAYHORN stated that "it was more entertaining than the real housewives." STRAYHORN felt like she was watching a weekly show and would wonder "What are they up to this week?" STRAYHORN stated that it was "pretty unusual" and that she has never done it before.

Most of the videos that STRAYHORN watched was led by NADER POURHASSAN (POURHASSAN). There were times when POURHASSAN was joined by Kush Dhody (Dhody) and Scott Kelly (Kelly). STRAYHORN never saw Kazem Kazempour (Kazempour) on the videos. Outside consultants, such as Dr. Jacob Lalezari (Lalezari) would sometimes join via telephone. The interviewer would regularly pull customers or clients to join the conversations via telephone. STRAYHORN went down to all sorts of different paths, including Investors' Hub and DrBeen's videos/medical show.

Kazempour was the primary point of contact at Amarex and Amarex was CYTODYN's representative. STRAYHORN communicated mainly with Kazempour. There were times when Kazempour was not available, and Kush would cover for KAZEMPOUR. There was also another female who covered for Kazempour when he was not available, but STRAYHORN did not remember her name.

STRAYHORN might have had one interaction with POURHASSAN. When STRAYHORN emailed Kazempour about the BLA submission not being complete, STRAYHORN might have "cc'd" POURHASSAN in the email. Other than that, STRAYHORN did not have direct contact/communications with POURHASSAN.

STRAYHORN referred to her notes and stated that on April 6, 2021, the FDA received a notification that CYTODYN wanted to change the regulatory contact. The request listed Chris Recknor (Recknor) as the new primary point of contact, but the letter stated to continue to "cc" Kazempour on all communications. STRAYHORN did not have direct communications with CYTODYN. All communications were sent to Amarex.

The Form 1571 is where a sponsor can list their regulatory representative and identified FDA's primary point of contact. FDA can only communicate to whoever is in that form. FDA follows a strict pathway of communications on who to reach out to. Kazempour was listed as the primary contact, but was later changed to Recknor, then to Dana Dunn.

During the time period in question, the regulatory contact for CYTODYN was Kazempour, and Kazempour was designated as CYTODYN's representative for the purposes with the FDA.

Kazempour was the representative for CYTODYN, but STRAYHORN did not know who Kazempour communicated with at CYTODYN. FDA's expectation of Kazempour depended on the situation or type of study. If there was a concern from the FDA, the FDA expects the CRO to notify the sponsor right away. For serious adverse events, the sponsor must notify the FDA immediately. STRAYHORN stated that sometimes it also depends on the contract, and that if it was a cheap contract, the sponsor might only get a weekly or monthly update from the CRO. The contract would usually list the expectations of the CRO. As CRO, you want to be transparent and not withhold information. Amarex was responsible for pretty much everything except sometimes medical monitoring – that responsibility was shared between CYTODYN and Amarex.

In communications with Kazempour, STRAYHORN's expectation was that Kazempour conveyed information to CYTODYN. STRAYHORN was not sure if that was being done and that POURHASSAN might not have the experience and relied on everything to the CRO.

Based on STRAYHORN's observations during in-person meetings held at the FDA, it is her opinion that maybe POURHASSAN might not have a lot of experience in clinical trials and that he relied on Amarex's expertise. STRAYHORN stated that POURHASSAN attended several in-person meetings at the FDA. According to STRAYHORN, POURHASSAN would usually sit in the back, behind the Amarex

representatives, or on the side. POURHASSAN never spoke or answered/asked questions and relied on Amarex to lead the meetings.

According to STRAYHORN, POURHASSAN never missed a face-to-face meeting. STRAYHORN could not tell if he ever missed a telephonic or a video conference meeting. According to STRAYHORN, "Nader was literally there, but never spoke."

There are two ways to submit a BLA. One way is to submit the whole BLA application package all at once or submit under the rolling review. Once all the modules of the BLA are submitted, the FDA has 60 days to determine if it is eligible for filing and therefore deemed, as "filable." At that time, no real review is conducted. Once it is determined that the BLA package is "filable," the FDA will start its formal review, which can take approximately 6-10 months.

On March 15, 2019, CYTODYN failed to include the user fee and an Unacceptable for Filing Letter (UN Letter) was issued on March 27, 2019. CYTODYN was later approved for a small business user fee waiver, for which CYTODYN then resubmitted on July 31, 2019.

The FDA felt that CYTODYN was taking advantage of the rolling submissions by "putting little extras." The non-clinical module was supposed to be completed when submitted – there was no agreement of submitting the module at a later date. On the April 27, 2020 submission, portions of the clinical module were missing. The datasets, which were a major part of the submission, were missing. In a rolling review, when a module is submitted, it is expected for that module to be complete. STRAYHORN was certain that those requirements were mentioned during the pre-BLA and NDA meetings with CYTODYN. STRAYHORN did not recall anyone conveying or querying that they did not understand those fundamental requirements.

In 2016, CYTODYN was granted a Fastrack Designation (FTD). Not everyone is eligible for a FTD, but because CYTODYN was pursuing a HIV heavily treatment-experienced (HTE) patients, they did not want the patients to run out of drugs. And as result of the FTD being granted, CYTODYN were also granted the rolling review. STRAYHORN stated that there was a concern that CYTODYN will take advantage of the rolling review, where they will continue the process of "Oops! I forgot this…forgot that…"

At some point, any verbal communications with Amarex ended. There was no real reason to stop, but the FDA wanted to carefully spell out their communications with CYTODYN. STRAYHORN did not think Amarex/CYTODYN were reading or understanding what was being asked. FDA tried to help CYTODYN/Amarex and started to "itemize" and listed specific issues on their communications. The IRs and other communications became very detailed to protect the FDA.

Type-A meetings allowed sponsors to have follow-up questions. After the BLA Return to File (RTF), CYTODYN had an opportunity to ask for clarifications for details from the FDA though the Type-A meeting. STRAYHORN did receive some request for clarifications, but not during the meetings. STRAYHORN received some request for clarifications, but not a lot.

• Document 2019.12.14_DOJ-FDA-0000023583

The letter outlined specific and potential "Refuse to File" issues and a reminder of what needed to be completed prior to the submission of the BLA.

This is an example of minutes that STRAYHORN wrote after meeting with CYTODYN and Amarex. STRAYHORN shared the minutes with Amarex. The minutes were written in "great detail to make sure they understood what was being asked and to avoid the 'he said- she said situation.'" FDA's written minutes to all meetings is what FDA considered as "official minutes." Some companies write their own minutes, but CYTODYN did not. With other sponsors, the minutes were usually written using bullet points and were written at a very high level. With CYTODYN, the minutes were written in more extensive detail– this is something that the FDA do not normally do. STRAYHORN did not think CYTODYN knew what they were doing and that Amarex seemed like a young CRO and also did not know what they were doing.

The detailed minutes was not exclusive to CYTODYN. The FDA tried to do the same with smaller firms to make sure they understood what was being communicated and that sometimes smaller companies needed more guidance.

• Page 7 – "Definite RTF issues: The following are refuse-to-file (RTF) issues if not addressed at the time of the BLA submission: A. Failure to submit an agreed-upon iPSP. B. Failure to submit results from an agreed-upon Human Factors Study. C. Failure to submit the following CMC information."

iPSP or Pediatric Study Plans should have been completed and agreed upon with the FDA prior to submitting the BLA. The chemistry, manufacturing and control (CMC) had their own separate module. Human Factors Study should be included in the clinical module. STRAYHORN felt like the FDA was constantly reminding CYTODYN of the components of the "definite RTF issues" and what was needed to be completed prior to submitting the BLA.

From STRAYHORN's memory, it did not appear that POURHASSAN understood. During the in-person meetings at the FDA, POURHASSAN never spoke or asked questions. STRAYHORN stated that POURHASSAN "might have whispered [questions] to an Amarex person who was sitting in front of him, but she was not certain. Kazempour or Dhody did not ask for clarifications during meetings.

• Page 6, Paragraph 3 – "CytoDyn would like to continue to target the end of March 2019 for the submission of the final component of their BLA. The Division expressed concern that this timeline may be overly optimistic and encouraged CytoDyn to take the time necessary to prepare for an adequate and well-constructed submission."

STRAYHORN remembered the discussion. STRAYHORN stated that CYTODYN were in a hurry trying to get the BLA done. This was FDA telling CYTODYN to "Slow down. Let's get the data right. Don't rush."

The FDA became aware that CYTODYN issued a PR in regard to the CD03 trial and stated that the 700 mg dose was much more efficient than the 350 mg dose while maintaining low viral load. CYTODYN did not share this information with the FDA. The FDA had grave concern that the HTE patients had limited treatment options and CYTODYN wanted to submit the BLA based on the lower dose of 350 mg, but then tell the public that the 700 mg was better. The FDA offered suggestions and help on how to design their clinical trial for the HTE patients for the 350 mg dose. The FDA was concerned that they were in such a hurry to go with the 350 mg dose and get a BLA at the expense perhaps of vulnerable patient population. The FDA was trying to suggest different aspects to help them out. STRAYHORN agreed that a new clinical trial would prolong the BLA submission.

STRAYHORN stated that CYTODYN's timeline was unrealistic. STRAYHORN felt that they were rushing and "trying to take the short cut."

• Document 2018.12.28_DOJ-FDA-0000021791

STRAYHORN was directed to review the 1st paragraph - "We are reviewing the email communication you sent the Division on December 21, 2018. Before we can address your request, we want to ensure that you fully understand the advice we have provided and that we fully understand your current and expected trial data."

This was as communication from the FDA to Kazempour to further clarify what was needed to file the BLA and "telling them to slow down."

STRAYHORN was directed to the following sections of the document:

• "First, we are concerned that you are operating on an overly optimistic timeline for your BLA submission."

• “Second, we want to remind you that you will need to submit the following information with you BLA submission.”

The paragraph listed what needed to be submitted and completed before submitting a BLA.

• “Third, we are having difficulty reconciling the CD03 data you have provided us via IR with the data presented in your press release.”

The document was alluding to some of the issues that needed to be addressed. The FDA do not always receive requested data or information from CYTODYN. The FDA did not receive data on the 700 mg dose study that they have conducted as mentioned on the PRs. The information on the PRs were inconsistent to what was provided to the FDA.

• Document 2019.01.03_DOJ-FDA-0000042747 - Response letter from CYTODYN to FDA

The document discussed and recapped on the overly optimistic timeline for the BLA submission.

• Top of Page 2 - Response: “Thank you for your feedback. We appreciate the Division’s comments and we will take them into consideration while submitting the updated BLA timeline under the revised rolling review request (expected to be submitted early January 2019). Please note that we are allocating adequate time for cleaning, analysis and clear presentation in the BLA. The details of our proposal timelines will be outlined in the resubmission of the rolling review request.”

CYTODYN, through its representative, Amarex, acknowledged that they received the letter and acknowledged that they are operating on an overly optimistic timeline for the BLA submission.

• Middle of Page 2 - Response: “Thank you for summarizing the list of information to be included in our BLA submission associated with the change in proposed PRO 140 dosing. All your valuable comments will be taken into consideration while submitting the revised timelines for rolling review request.

CYTODYN, through its representative, Amarex, stated that they understood what was needed for the BLA submission.

• Bottom of Page 2 - “Summary of Response to Item #1 to #5” to the third issued addressed by the FDA:

CYTODYN, through its representative, Amarex, acknowledged FDA’s concerns as outlined on the IR.

STRAYHORN was not sure if it was POURHASSAN’s/CYTODYN’s or Kazempour’s/Amarex’s “naivete” was the reason for the incomplete BLA submission. During the in-person FDA meetings, CYTODYN was not involve and they were just in the background. It was unusual to see sponsors just be in the background. CYTODYN did not say anything, and STRAYHORN could tell that they had 100% reliance on Amarex. CYTODYN did not challenge or asked questions. STRAYHORN assumed CYTODYN saw the minutes, but if they needed clarity on certain issues, they never reached out.

The FDA provided guidance documents on what should be on a BLA for sponsors and CROs to read. The FDA also provided clear directives, that were conveyed repeatedly on minutes and IRs on what should be completed for the rolling review and the fundamentals of a BLA submission. Amarex mentioned on their website that they have submitted BLAs in the past and therefore Kazempour "should know what is on a BLA." STRAYHORN agreed that there is no “naivete” in those regards.

• Documents 2019.10.24_DOJ-FDA-0000045550; 2019.10.24_DOJ-FDA-0000045551; and 2019.10.30_DOJ-FDA-0000043888:

Email response from Kazempour: “I received the IR dated October 24, 2019, and I shared it with the Sponsor and also internally with the team here at Amarex. And we will address all the CMC, Human Factor and

Combination Product comments in the BLA submission."

The email is an example of Kazempour acknowledging that the issues and components needed to be addressed prior to submitting the BLA. Kazempour indicated that he understood and that they would do it. Kazempour communicated the information and confirmed that he had shared the IR with CYTODYN.

• Document 2020.04.29_DOJ-FDA-000002730, Email Re: BLA 761144 – Remains Incomplete

STRAYHORN recalled the email. This type of email was unusual. STRAYHORN has never sent such an email ever.

The email was sent to Kazempour to alert Kazempour that the BLA was not complete and that the PR that CYTODYN issued to the public was not accurate. On the PR, CYTODYN was claiming that the April 27 was the submission date and therefore the clock should start on April 27th, when that was not the case since the BLA that was submitted was not complete. The clock starts when a completed BLA was submitted. People reading the PR might say that the FDA is not doing their job.

• Second bullet on the paragraph – "The BLA application is not considered complete as you yourself acknowledged in your covering letter with the April 27, 2020, submission – noting that the clinical datasets remain outstanding."

CYTODYN/Amarex acknowledged on their cover that the BLA was not complete.

It was important to address the PR because of the misinformation of the BLA timeline. A lot of people are tracking the drug and in a sense the FDA wanted to stop the "rolling rolling rolling review." POURHASSAN issued a PR and the FDA wanted to let the CRO know "that we [FDA] don't agree."

• Document 2020.04.30 – Email Re: BLA 761144 – Remains Incomplete - "This is to let you know that I received your email, and I am talking with the team here and will let Cytodyn know about this email."

• "As the regulatory agent on behalf of CytoDyn our expectation is that you have communicated this information to CytoDyn. We ask you to take regulatory responsibility for the misinformation released in the aforementioned Press Release by notifying CytoDyn."

There was misinformation going out there in regard to when the BLA was submitted. The FDA was concerned that if this is the date CYTODYN was claiming as the submission date, then they were already behind the review clock. Timeline was important to the FDA to preserve the integrity of the filing process.

• Document 2020.04.30 – Email, Kazempour response to STRAYHORN re BLA 761144 – Remains Incomplete

• "This is to let you know that I have received your email and I am talking with the team here and will let CytoDyn know about his email."

STRAYHORN recalled sending the email. STRAYHORN stated that she "never sent such an email ever" and that it was "unusual."

According to the email, Kazempour received the email and relayed the information to CYTODYN. STRAYHORN did not recall if anyone from CYTODYN or Amarex reached out to the FDA after this email.

The interview concluded at approximately 9:48 AM (PT).

SUBMITTED: Electronically submitted by MARIDEHL MATHER

MARIDEHL MATHER, SPECIAL AGENT DATE: 11/22/2022

APPROVED: Electronically approved by MICHAEL KWAN

MICHAEL KWAN, RESIDENT AGENT IN CHARGE DATE: 11/22/2022

DISTRIBUTION: ORIG:SFC

ATTACHMENTS: 2021.05.17 Statement on Leronlimab_FDA
2018.12.28_DOJ-FDA-0000021791
2019.01.03_DOJ-FDA-0000042747
2019.10.24_DOJ-FDA-0000045550
2019.10.24_DOJ-FDA-0000045551
2019.10.30_DOJ-FDA-0000043888
2019.12.14_DOJ-FDA-0000023583
2020.04.29_DOJ-FDA-0000002730
2020.04.30 re BLA 761144 - Remains Incomplete